Fresenius Medical Care

Phillip J. Phillips
Deputy Director for Science and Regulatory Policy
Office of Device Evaluation
Food and Drug Administration
9200 Corporate Blvd., HFZ 400
Rockville, MD 20850

December 4, 2002

RE: Draft Guidance Pertaining to Medical Devices Made with PVC Containing DEHP

Dear Mr. Phillips,

This letter is in response to the request for comments on FDA's draft document, Guidance Pertaining to Medical Devices Made with PVC Containing DEHP, dated September 6, 2002. Fresenius Medical Care, North America, recognizes the honorable intent of the FDA to alert the public to the risks of exposure to high levels of DEHP that may leach out of plastic medical devices over time. However, we are concerned that the language in this document infers that the use of dialysis tubing and devices, made with PVC containing DEHP, compromises the health of dialysis patients. The draft guidance also recommends that manufacturers reduce patient exposure by using alternate materials. Fresenius feels that this language in this document is confusing and causes undue concern to the dialysis community. It is also inconsistent with FDA's publication, Safety Assessment of Di (2-ethylhexyl) phthalate (DEHP) Release from PVC Medical Devices. Accordingly, we would like to point out the following:

Benefits versus Risks

Dialysis is a critical and life saving treatment. Without it, patients with end stage renal disease (ESRD) will certainly die. The medical community is very familiar with this type of analysis, as almost all devices and drugs carry some degree of risk. It is well known that the benefits of dialysis far outweigh the potential risk of using devices made of PVC containing DEHP.

Safety

1. PVC devices containing DEHP have been used successfully for dialysis treatments for over 30 years. Devices used for dialysis do not expose patients to significant levels of DEHP. Although dialysis requires daily (PD) or multiple treatments per week (Hemo), exposure to DEHP is limited, since new devices are used for each treatment and blood or fluid contact time with PVC is minimized. To date, we have no substantial evidence to suggest serious illnesses relating to DEHP exposure from dialysis treatments.

2. FMC focuses on using biocompatible materials in their devices. FMC has extensive biocompatibility data supporting the biological safety of PVC materials containing DEHP.

3. These materials have been tested per ISO 10993-1 and USP standards, which are recognized by the FDA. No material, used in our devices, has ever failed these tests.

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4. FMC uses aging studies to ensure that our devices using compounded PVC formulas do not leach significant amounts of plasticizer over the shelf life of the product.

Efficacy

DEHP plasticizer enhances the physical properties of PVC tubing and containers necessary for optimal dialysis treatments. We continue to evaluate non-PVC materials as alternatives. So far, most of these materials were found to be less than optimal since they were not as flexible or were difficult or impossible to bond securely. The importance of flexibility and secure bond strength is critical in dialysis treatment since blood cell rupture, or blood loss can have devastating results.

Prohibitive Cost

A change to different materials would result in prohibitive costs to both the Device and Health Care Industries. With fixed reimbursement cost provided by Medicare/Medicaid, these cost increases would be passed on to the patient.

Since the FDA (CDRH) has already published Safety Assessment of DEHP Released from PVC Medical Devices, in which it clearly evaluates the risks of DEHP exposure, Fresenius Medical feels that information in the above document is sufficient guidance and that the September 6 draft guidance is unnecessary and should be withdrawn.

Sincerely,

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cc: Docket No. 02D-0325
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